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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,934	06/15/2001	Douglas Shytle	LAY-011CIA	9442

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,934	SHYTLE ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/3/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Applicant's election with traverse of group IV, claims 16-20 in the Paper received 05 January 2004 is acknowledged. The traversal is on the ground(s) that the claims in Groups II, III and IV are all neuropsychiatric disorders, and as such should be examined together because it does not appear that this would impose any undue burden on the examiner. Per the conversation with Carl Massey on 06 January 2004, the examiner has agreed to examine the claims of Group III along with the claims of Group IV (claims 12-20), however, Group II remains restricted.

Claims 1-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement the Paper received on 05 January 2004.

Claims 12-20 are presented for examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crooks et al. U.S. Patent No. 5,691,365 A. in view of The Merck Manual (U)

The claims are drawn to a method of treating Tourette Syndrome and neuropsychiatric disorders selected from bipolar disorder, depression, anxiety disorder, schizophrenia, seizure disorder, Parkinson's disease and attention deficit hyperactivity disorder comprising administration of a therapeutically effective amount of exo R mecamylamine or a pharmaceutically acceptable salt thereof, which is substantially free of exo S mecamylamine.

Crooks et al. teach nicotine analogs that have nicotinic receptor antagonist properties, that are useful in treatment of cognitive disorders such as Parkinson's disease (see abstract). It does not teach treatment of Tourette Syndrome, however, it would have been obvious to employ a nicotine receptor antagonist such as mecamylamine to treat symptoms of Tourette Syndrome motivated by the teaching of Crooks et al. who teaches treatment of Neurologic disorders such as Parkinson's disease with nicotine receptor antagonists and the Merck Manual that teaches that dyskinesia's such as Tourette Syndrome are due to basal ganglia disorders (a neurologic disorder).

The patent does not teach treatment with the R isomer that is substantially free of the S isomer. It would have been obvious to employ the R isomer that is substantially free of the S isomer. As legal authority in this case the examiner cites *In re Adamson and Duffin* 125 USPQ 233. The case sets forth the requirements of patentability with regard to stereoisomers as follows:

1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See the first paragraph on page 235.

2) One skilled in the art expects that individual stereoisomers will differ significantly in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process certain stereochemical configurations

over others. See page 234, the third full paragraph and page 235, the fifth full paragraph on the page.

See also *In re Anthony* 162 USPQ 595 and *In re May and Eddy* 192 USPQ 601.

Note: claims must specify "isolation", "optical purity", etc or they are read upon by the racemate.

Claims 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over University of South Florida Research Foundation WO 99/07378 A1.

The claims are drawn to a method of treating Tourette Syndrome and neuropsychiatric disorders selected from bipolar disorder, depression, anxiety disorder, schizophrenia, seizure disorder, Parkinson's disease and attention deficit hyperactivity disorder comprising administration of a therapeutically effective amount of exo R mecamylamine or a pharmaceutically acceptable salt thereof, which is substantially free of exo S mecamylamine.

University of South Florida teaches administration of a nicotine antagonist, particularly mecamylamine (see abstract) and mecamylamine stereoisomers (see claim 8) for neuropsychiatric disorders such as Tourette syndrome, schizophrenia, depression, bipolar disorders, attention deficit hyperactivity disorder, and obsessive-compulsive disorder.

It does not teach the R stereoisomer. It would have been obvious to employ the R isomer that is substantially free of the S isomer. As legal authority in this case the

examiner cites *In re Adamson and Duffin* 125 USPQ 233. The case sets forth the requirements of patentability with regard to stereoisomers as follows:

1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See the first paragraph on page 235.

2) One skilled in the art expects that individual stereoisomers will differ significantly in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process certain stereochemical configurations over others. See page 234, the third full paragraph and page 235, the fifth full paragraph on the page.

See also *In re Anthony* 162 USPQ 595 and *In re May and Eddy* 192 USPQ 601.

Note: claims must specify "isolation", "optical purity", etc or they are read upon by the racemate.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 9:00 A.M. - 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
Patent Examiner
Art Unit 1614

5/3/04

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